

Interview SummaryApplication No.
09/247,054

Applicant(s)

Antoniou et al.Examiner
Anne-Marie Baker, Ph.D.Group Art Unit
1632

All participants (applicant, applicant's representative, PTO personnel):

(1) Anne-Marie Baker, Ph.D.(3) Doreen Trujillo(2) Karen Hauda

(4) _____

Date of Interview Jul 13, 2001Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy is given to 1) ☐ applicant 2) ☐ applicant's representative]Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No. If yes, brief description:Claim(s) discussed: 1-21, 23, and 25

Identification of prior art discussed:

Safaya et al. (1994)Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

The Supervisory Patent Examiner (Karen Hauda) pointed out that the claims are not patentable over Safaya et al. because the plasmid of Safaya et al. has all the structural elements recited in the claims. Applicants' representative argued that the plasmid of Safaya et al. is a non-replicating plasmid, that it does not contain a self-replicating origin of replication, and that it cannot confer tissue-specific expression because it contains only the HS2 site. First, the Examiners questioned how a plasmid could be non-replicating and what is meant by a "self-replicating origin of replication." The Examiners argue that all plasmids must have an origin of replication. Second, the Examiners pointed out that in the Declaration of Dr. Robert Crombie, filed April 6, 2001, Applicants have completely reversed their position regarding the function of the HS2 site. In paragraph 12, the Declarant states that the presence of the HS2 site alone is sufficient to confer tissue-specific expression. (continued on attached sheet)

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☐ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached

*Anne-Marie Baker***ANNE-MARIE BAKER
PATENT EXAMINER**

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Art Unit: 1632

Interview Summary

(cont.) Further, the Examiners pointed out that the recitation in the preamble “for expressing a gene of interest in a host cell of a specific tissue type” is only an intended use, and that the properties of the claimed composition are inherent. Thus, when a composition meets the structural limitations of the claim, the claimed properties or functions are presumed to be inherent. Applicants’ representative further argued that a plasmid that only replicates in bacteria, such as the plasmid of Safaya et al., cannot satisfy the claim language that recites tissue-specificity, and therefore does not satisfy all the limitations of the claim. Applicants’ representative stated that she would find out which origin of replication the plasmids of Safaya et al. use and would submit this evidence to the Examiner. The Examiners stated that prosecution in this application would be re-opened to make the new grounds of rejection. The Examiners further stated that Claims 3, 4, 5, 14, 15, and 16 would be allowable with some minor modifications to the claim language, if re-written in independent form, as these claims recite specific components of the β -globin LCR.